

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

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) C.A. No. 06-164 (SLR)
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NOTICE OF SUBPOENA AD TESTIFICANDUM & DUCES TECUM

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, defendants Apotex Inc. and Apotex Corp. ("Apotex") has served or will serve the attached subpoena and accompanying attachment on R.D. Sofia, Ph.D., 82 Fairview Ave., Lancaster, Pennsylvania, 17603-5543. Please be advised that the examination will be conducted before a person duly authorized and may be recorded by stenographic and videographic means. You are invited to attend and cross-examine.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

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*Counsel for Defendants Apotex Inc. and
Apotex Corp.*

Dated: April 25, 2007
791383 / 30136

AOSS (Rev. 12/06) Subpoena in a Civil Case

Issued by the
UNITED STATES DISTRICT COURT
 EASTERN DISTRICT OF PENNSYLVANIA

MEDPOINTE HEALTHCARE INC.
 Plaintiff

SUBPOENA IN A CIVIL CASE

V.
 APOTEX INC. and APOTEX CORP.
 Defendant

Case Number: ¹ 06-164-SLR
 District of Delaware

TO: R.D. Sofia, Ph.D.
 82 Fairview Ave.
 Lancaster, PA 17603-5543

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION Paul & Paul, Two Thousand Market St., Suite 2900, Philadelphia PA 19103	DATE AND TIME 5/4/2007 10:00 am
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☒ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

Specified in the attached Schedule A, a true and correct copy of which is attached hereto and incorporated by this reference.

PLACE Paul & Paul, c/o Alex R. Sluzas Two Thousand Market Street, Suite 2900, Philadelphia, PA 19103	DATE AND TIME 5/3/2007 9:00 am
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☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT) Attorney for the Defendant	DATE 4/24/2007
---	-------------------

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
 Stephen P. Benson
 120 S. Riverside Plaza, 22nd Floor
 Chicago, IL 60606
 (312) 655-1500

(See Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), on next page)

¹ If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 12/06) Subpoena in a Civil Case

PROOF OF SERVICE

DATE:

PLACE:

SERVED

SERVED ON (PRINT NAME)

MANNER OF SERVICE

SERVED BY (PRINT NAME)

TITLE:

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on

DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Subdivisions (c), (d), and (e), as amended on December 1, 2006:

(C) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises — or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information; or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party; or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject

to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(D) DUTIES IN RESPONDING TO SUBPOENA.

(1) (A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

Schedule A

I. Definitions

1. **'194 Patent.** The term "'194 Patent" means U.S. Patent No. 5,164,194.
2. **Apotex.** As used herein, the term "Apotex" refers to the defendants Apotex Inc. and Apotex Corp., including any of its divisions, departments, subsidiaries, parents, affiliates or predecessors, or any present or former officer, partner, director, attorney or agent of Apotex, and all other persons acting or purporting to act on behalf of Apotex.
3. **Asta.** As used herein, the term "Asta" refers to Asta Pharma AG, Asta Medica AG, Viatrix, Degussa and (i) all their predecessors-in-interest and successors-in-interest; (ii) all past or present corporate parents, subsidiaries, affiliates divisions, officers, directors, employees, agents, consultants, investigators, attorneys, and representatives; (iii) any other person acting on their behalf or on whose behalf they have acted or are acting; or (iv) any other person or entity otherwise subject to their control or which controls or controlled them. Where applicable, this definition shall include all persons having a former or current ownership interest in the '194 Patent.
4. **Azelastine.** The term "Azelastine" is defined to be synonymous with its description in U.S. Patent No. 5,164,194. Where appropriate this definition includes physiologically acceptable salts of Azelastine.
5. **Carter Wallace.** The term "Carter Wallace" refers to Carter Wallace, Inc., Carter Wallace Laboratories, Wallace Laboratories, and any related entities, partners, corporate parents, subsidiaries, affiliates, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and persons acting or purporting to act on their behalf. Where

applicable, this definition shall include all persons having a former or current ownership interest in the '194 Patent.

6. **Communication.** The term "Communication" means the transmittal of information in the form of facts, ideas, inquiries, or otherwise.

7. **Concern(s), Concerning, Concerned with, Relate(s) or Relating to.** The terms "Concern(s)", "Concerning", "Concerned with", "Relate(s)", or "Relating to" are used interchangeably and mean concerning, evidencing, pertaining to, referring to, mentioning, memorializing, commenting on, containing, identifying, connected with, contemplating, discussing, stating, describing, reflecting, dealing with, consisting of, constituting, comprising, recording, or being relevant to all or any portion of the specified fact, conditions, events, or incidents.

8. **Date.** The term "Date" means the exact day, month and year, if known or ascertainable; if the exact day, month and year are not known or ascertainable, the most accurate temporal reference available.

9. **Document.** The term "Document" is synonymous in meaning and equal in scope to the usage of this term in Federal Rule of Civil Procedure 34(a), including, without limitation, electronic or computerized data compilations. A draft or non-identical copy is a separate document within the meaning of this term. "Document" also includes and refers to the file or any container holding of which once held any documents, as well as to any writing or printing which might appear on such file or container.

10. **Eisai.** The term "Eisai" refers to Eisai Co., Ltd., Eisai Inc., and any related entities, partners, corporate parents, subsidiaries, affiliates, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and persons acting or purporting

to act on their behalf. Where applicable, this definition shall include all persons involved in the development, licensing, marketing, sale or offering for sale of any azelastine containing medicine.

11. Inventor. As used herein, the term "Inventor" means the named inventor of the '194 patent, Helmut Hettche, and/or Persons with a past or present ownership interest in the application which matured into the '194 patent and/or the '194 patent itself, including, without limitation, Asta Pharma AG, Asta Medica AG, Viatris, Degussa and (i) all their predecessors-in-interest and successors-in-interest; (ii) all past or present corporate parents, subsidiaries, affiliates divisions, officers, directors, employees, agents, consultants, investigators, attorneys, and representatives; (iii) any other person acting on their behalf or on whose behalf they have acted or are acting; or (iv) any other person or entity otherwise subject to their control or which controls or controlled them.

12. Person. The term "Person" is defined as any natural person or any business, legal or governmental entity or association, and any functional division thereof.

13. You. The terms "You" or "Your" refer to Robert D. Sofia and any past or present employees, agents, representatives, or attorneys with involvement with the development of azelastine containing medicaments, or with knowledge, possession, custody or control of any Documents relating to the production of azelastine containing medicaments.

II. Instructions

1. The following **rules of construction** apply to these Document requests, definitions, and instructions:

- (a) **All/Each/Any.** The terms "all," "each," and "any" shall be construed as inclusive and synonymous and are as inclusive in scope as permitted by the Federal Rule of Civil Procedure.

(b) **And/Or.** The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the request all responses that might otherwise be construed to be outside of its scope.

(c) **Number.** The use of the singular form of any word includes the plural and vice versa.

(d) **Independence.** Except as otherwise expressly directed herein, each paragraph and subparagraph of a document request shall be construed independently and not by reference to any other paragraph or subparagraph herein for the purpose of limiting the scope of the document request being responded to.

2. Each request to produce documents shall be construed to request documents within your possession, custody, or control. Separately for each Request, if any Document responsive to that Request once was in your possession, custody, or control but has been lost, discarded, destroyed, or is otherwise presently not within your possession, custody, or control:

(e) identify the unavailable Document;

(f) identify any and all persons who lost, discarded, or destroyed the Document or caused the document to become otherwise unavailable;

(g) identify any and all persons likely to have knowledge concerning the circumstances by which the Document was lost, discarded, destroyed, or otherwise became unavailable;

(h) identify any and all persons likely to have knowledge concerning the contents of the Document that was lost, discarded, destroyed, or otherwise became unavailable.

3. When producing Documents, You should organize and label them to correspond with the numbered categories in this Request and where applicable, the order and organization of Documents within each category should reflect the manner in which such documents are maintained in the usual course of business.

4. Please produce all Documents maintained or stored electronically in native, electronic format with all relevant metadata intact and in appropriate and useable manner. Encrypted or password protected Documents should be produced in a form permitting them to be reviewed.

5. If You find the meaning of any terms in these requests unclear, You shall assume a reasonable meaning, state what the assumed meaning is, and respond to the request according to the assumed meaning.

6. If You object to any request or part of any request, the reason(s) for the objection shall be stated in full. If an objection is made to any request, production should be made of all Documents or things to which the objection does not relate.

7. If You withhold any information, Document or thing otherwise discoverable under the Federal Rules of Civil Procedure on the basis of privilege and/or the work product doctrine, the following information is requested:

- (i) the privilege and/or work-product rule of law being relied upon;
- (j) the date the Document was created;
- (k) the identity of the person or persons who created the information, Document or thing;
- (l) the identity of the present custodian of the information, Document or thing;
- (m) the identify any and all persons to whom the information, Document or thing was or has been sent, distributed, forwarded, copied, told, or communicated in any manner, stating the job title and/or position of that person;
- (n) the subject matter of the information, Document or thing; and
- (o) the location of the information, Document or thing.

8. These requests are continuing in character, so as to require you to file supplemental responses in accordance with Rule 26(e) immediately upon obtaining additional documents or things or different information which makes a prior response no longer full, complete, correct or true.

9. If any document required to be produced in response to a request is no longer in your possession, custody or control or within the possession, custody or control of your attorney,

agent, employee, investigator or representative, state whether such document or thing is missing or lost, has been destroyed, has been transferred, voluntarily or involuntarily, to others, or has otherwise been disposed of; and in each instance, explain in detail the circumstances surrounding any authorization to make such disposition of the document or thing and the date thereof.

III. Documents or Things to be Produced by Robert D. Sofia

1. All documents relating to the development of azelastine containing medicaments, including but not limited to all tablets, capsules, solutions, ointments, salves, suppositories, drops, sprinkles, aerosols, and syrups. Responsive documents include but are not limited to all notebooks, memoranda, research reports, abstracts, invention disclosures, and other documents concerning development of azelastine containing medicaments.
2. All documents relating to any attempts to obtain regulatory approval to market and/or sell azelastine containing medicaments in the United States, Japan, Germany, Australia, Ireland, Spain, or any and all other countries or territories.
3. All documents relating to all applications of any azelastine containing solutions, ointments, powders, drops, salves or sprays directly to the nasal mucosa and/or eye of any research animal or study participant, including but not limited to humans, guinea pigs, rats, dogs, rabbits and mice.
4. All documents relating to all applications of aerosolized azelastine containing solutions to research animals or study participants, including but not limited to humans, guinea pigs, rats, dogs, rabbits and mice.
5. All documents relating to any team meeting held between Asta, Carter Wallace, Eisai and/or MedPointe relating to the development of azelastine containing medicaments in the forms

of tablets, capsules, solutions, ointments, powders, salves, suppositories, drops, aerosols, and syrups.

6. All documents relating to or constituting any communication between Yourself and Asta including but not limited to all communications concerning the obtaining of regulatory approval to make and sell azelastine containing medicaments in any country or territory. Responsive documents include all communications wherein You or Asta were a direct or indirect recipient of the subject communication, including but not limited to all distribution documents or documents identifying Yourself or Asta as a carbon copy (*i.e.* cc) recipient.

7. All documents relating to or constituting any communication between Yourself and Carter Wallace including but not limited to all communications concerning the obtaining of regulatory approval to make and sell azelastine containing medicaments in any country or territory. Responsive documents include all communications wherein You or Carter Wallace were a direct or indirect recipient of the subject communication, including but not limited to all distribution documents or documents identifying Yourself or Asta as a carbon copy (*i.e.* cc) recipient.

8. All documents relating to or constituting any communication between Yourself and MedPointe including but not limited to all communications concerning the obtaining of regulatory approval to make and sell azelastine containing medicaments in any country or territory. Responsive documents include all communications wherein You or MedPointe were a direct or indirect recipient of the subject communication, including but not limited to all distribution documents or documents identifying Yourself or Asta as a carbon copy (*i.e.* cc) recipient.

9. All documents relating to or constituting any communication between Yourself and Eisai including but not limited to all communications concerning the obtaining of regulatory approval to make and sell azelastine containing medicaments in any country or territory. Responsive documents include all communications wherein You or MedPointe were a direct or indirect recipient of the subject communication, including but not limited to all distribution documents or documents identifying Yourself or Asta as a carbon copy (*i.e.* cc) recipient.

10. All documents relating to or constituting any communication between Yourself, Asta, Carter Wallace, Eisai and/or MedPointe, including but not limited to all communications concerning the coordination of development of azelastine containing medicaments.

11. All documents relating to or constituting any communication between Yourself, Asta, Carter Wallace, Eisai and/or MedPointe, including but not limited to any request for or offering of information or advice to any individual concerning the formulation of any azelastine containing medicament.

12. All documents relating to or constituting any communication between Yourself, Asta, Carter Wallace, Eisai and/or MedPointe, including but not limited to all study protocols or results requested or offered concerning azelastine containing medicaments.

13. All documents concerning your role in coordinating joint research between Carter Wallace, Eisai and/or Asta, including but not limited to coordination of protocol methodologies resulting in the selection of antiallergic compounds for commercialization or approval of antiallergic compounds by any regulatory body of any country wherein regulatory approval is required to market, manufacture and/or sell azelastine containing medicines.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on April 25, 2007, the attached document was hand delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

Frederick L. Cottrell, III
Jameson A. L. Tweedie
Richards, Layton & Finger
One Rodney Square
P.O. Box 551
Wilmington, DE 19899

I hereby certify that on April 25, 2007, I have Electronically Mailed the foregoing document(s) to the following non-registered participants:

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